

Exhibit 1

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION) MDL 2804
OPIATE LITIGATION)
) Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:)
) Judge Dan Aaron Polster
Track One Cases)
) OPINION AND ORDER REGARDING
) DEFENDANTS' MOTIONS TO
) EXCLUDE OPINIONS OF JAMES
) RAFALSKI AND CRAIG MCCANN

Before the Court are two related *Daubert* motions filed by Defendants: (1) a Motion to Exclude the Opinions Offered by James Rafalski (**Doc. #: 1900**); and (2) a Motion to Exclude the Opinions and Testimony of Craig McCann (**Doc. #: 1906**). For the reasons stated below, the Court **GRANTS IN AND DENIES IN PART** the Motion to Exclude Rafalski (**Doc. #: 1900**) and **DENIES** the Motion to Exclude McCann (**Doc. #: 1906**).

* * * * *

Rafalski, a former Drug Enforcement Administration (“DEA”) investigator, offers opinions about, *inter alia*, the effectiveness of Defendants’ efforts to prevent the diversion of controlled substances into illegitimate channels. Rafalski identified five methods that a Distributor could use to identify potentially suspicious orders. In turn, McCann, a data expert, applied Rafalski’s methods to the DEA’s Automation of Reports and Consolidation Orders System (“ARCOS”) data and Defendants’ transactional data to identify transactions that meet the specified criteria of each methodology. Taken together, Rafalski and McCann provide opinions, as to

specific Defendants, regarding the number of orders to the *Track One* Counties that each method would have flagged as potentially suspicious.

Defendants ask the Court to exclude both opinions for a number of reasons, including unreliability, flawed assumptions, and lack of “fit” with issues in the case. Also, as to four of Rafalski’s opinions, Defendants assert Rafalski has not disclosed the basis for the opinions and may not testify as to legal conclusions. The Court agrees Rafalski must disclose the basis for his opinions, and he may not opine as to what the law requires or whether Defendants’ conduct violated the law. As to Rafalski’s remaining opinions, the Court finds Defendants’ attacks are unfounded. The Court’s reasoning is set forth below.

I. Rafalski.

A. Credentials and Experience.

Rafalski received an undergraduate degree in public administration from Eastern Michigan University in 1999. Rafalski Rpt., at ECF p. 4 (Doc. #: 1999-21).¹ In 2004, after 26 years as a law enforcement officer, Rafalski began work for the DEA as a Diversion Investigator in the Detroit Divisional Office, where he worked until June of 2017. *Id.* Diversion Investigators are responsible for conducting regulatory, state, civil, administrative, and criminal investigations. *Id.* From 2011 to 2017, Rafalski was primarily responsible for conducting administrative, civil, and regulatory investigations of DEA registrants. *Id.* In this capacity, he investigated the criminal

¹ Rafalski’s Report is also filed as an exhibit to Defendants’ Motion. *See* Defs. Mtn. to Excl. Rafalski, Ex. 1 (Doc. #: 1900-2). However, that document is missing pages 47 to 144. *See id.* Accordingly, the Court cites to the Report that Plaintiffs filed as an exhibit to their Notice of Corrected Filing of Expert Reports. *See* Notice, Ex. 21 (Doc. #: 1999-21). Because Doc. #: 1999-21 does not contain page numbers, the Court cites to the electronic court filing (“ECF”) pages.

conduct of individual physicians regarding improper opioid prescriptions and conducted regulatory investigations involving, *inter alia*, Distributors' compliance with DEA requirements regarding suspicious order monitoring systems ("SOMS"). *Id.* at ECF pp. 4-5.

For example, in 2006, Rafalski conducted an accountability audit, record-keeping review, and security investigation of a Walgreens in Ohio to ensure compliance with controlled substances regulations and record keeping. *Id.* at ECF p. 5. This investigation resulted in the DEA issuing a letter of admonition for the maintenance of an inadequate SOMS. *Id.*

From 2010 to 2013, Rafalski conducted an administrative investigation of The Harvard Drug Group to identify unusual patterns of distribution of oxycodone to Florida pain clinics. *Id.* at ECF p. 6. His work included the review of company records and policies, as well as the DEA's ARCOS data. *Id.* This investigation resulted in the DEA issuing an order to show cause for, *inter alia*, developing a work-around to avoid triggering the company's SOMS. *Id.*

Also, from 2010 to 2013, Rafalski conducted an administrative investigation of Masters Pharmaceutical, reviewing company files regarding customer due diligence, including questionnaires, on-site investigation reports, and SOMS information. This investigation resulted in the DEA revoking the company's registration to manufacture and/or distribute controlled substances. *Id.*; see *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

From 2010 to 2017, Rafalski conducted an administrative investigation of Mallinckrodt in which he reviewed chargeback data² that revealed some pharmacies and/or practitioners were utilizing multiple Distributors to purchase the same product in large quantities. *Id.* at ECF pp. 6-

² According to Rafalski, chargeback data or fee-for-services data provided by Distributors allows a Manufacturer to determine who purchased its drugs, in what volumes, and in which doses. See Rafalski Rpt. at ECF p. 146 (Doc. #: 1999-21).

7. As a result of this investigation, the DEA and Mallinckrodt entered into a three-year Memorandum of Agreement. *Id.*

Defendants do not challenge Rafalski's qualifications as an expert.

B. Opinions.

Rafalski expresses opinions about the compliance requirements for Manufacturers and Distributors to: (1) maintain effective controls to prevent diversion of controlled substances into illegitimate channels; (2) design and operate a system to identify suspicious orders (SOMS); and (3) report suspicious orders "when discovered."³ Rafalski Rpt. at ECF p. 10 (Doc. #: 1999-21). His opinions address four main categories:

- (1) what the law and DEA regulations require regarding the duties of Manufacturers and Distributors to maintain effective control against the diversion of controlled substances, *id.* at ECF pp. 9-21;⁴
- (2) key components and characteristics that make SOMS and due diligence programs effective, *id.* at ECF pp. 36-40;
- (3) five methodologies that, as calculated by Craig McCann (discussed below), identify "suspicious orders" that Defendants should not have shipped without conducting due diligence to dispel the suspicion of diversion, *id.* at ECF pp. 40-46; and

³ Under federal regulations, "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

⁴ Rafalski also discusses industry guidelines and provides a list of 32 "significant" DEA administrative actions against various Manufacturers and Distributors for failing to maintain effective control against diversion and identify and/or report suspicious orders. Rafalski Rpt. at ECF pp. 21-36 (Doc. #: 1999-21).

(4) the SOMS and due diligence practices of various Defendants and how they failed to comply with statutory and regulatory duties to maintain effective control against diversion, *id.* at ECF pp. 46-187.

Rafalski examined in detail the SOMS and due diligence procedures of six Distributors, concluding each violated its duty to maintain effective control against diversion, including duties to identify, report and/or stop shipment of suspicious orders.⁵ *See* Rafalski Rpt. at ECF pp. 9, 54-55, 68-69, 77-81, 91-93, 104-105, 120-121, 142-144 (Doc. #: 1999-21). Rafalski opines that these SOMS failures “directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances” that should never have been shipped “until after the suspicion of diversion was dispelled.” *Id.* at 40.

In addition, Rafalski examined the SOMS and due diligence procedures of seven Manufacturers, concluding each failed to meet its obligation to maintain effective controls against diversion.⁶ Rafalski opines that, to comply with their duty to maintain effective control, Manufacturers must use all relevant prescribing and chargeback data. *Id.* at ECF pp. 145-187.

C. Analysis.

Defendants ask the Court to exclude Rafalski’s testimony because: (1) he refused to disclose the basis for four of his opinions; (2) his methodology is based on faulty assumptions; and

⁵ The six Distributors are: Cardinal, McKesson, ABDC, CVS, Walgreen, and Henry Schein. Rafalski Rpt. at ECF pp. 46-145 (Doc. #: 1999-21). Rafalski selected these Distributors because, according to McCann’s calculations, they distributed a significant majority of the opioid pills delivered into Summit and Cuyahoga Counties. Rafalski Rpt. at 42 n.110 (Doc. #: 1999-21).

⁶ The seven Manufacturers are: Allergan, Janssen, Mallinckrodt, Purdue, Endo, Teva, and Insys. Rafalski Rpt. at ECF pp. 151-187 (Doc. #: 1999-21).

(3) he has no basis to conclude that all flagged orders were diverted for illicit use. *See* Defs. Mem. on Rafalski at 1 (Doc. #: 1900-1). The Court addresses each argument below.

1. Refusal to Disclose the Basis for Four Opinions.

Defendants urge the Court to exclude the following opinions because Rafalski has not disclosed the basis for them:

- (1) the law required Defendants to halt all shipments after identifying an initial suspicious order;
- (2) DEA regulations require certain “key components” regarding SOMS and due diligence systems;
- (3) the Controlled Substance Act (“CSA”) and its implementing regulations require Manufacturers to consider prescription and chargeback data; and
- (4) DEA registrants must document and permanently retain suspicious order reports and due diligence records.

See Defs. Mem. on Rafalski at 8 (Doc. #: 1900-1). Defendants also assert these opinions constitute impermissible legal conclusions. *Id.* at 8 n.3.

As to these four opinions, Defendants seek exclusion because Rafalski has refused to disclose the “legal guidance” he received from DEA attorneys that forms, at least in part, the basis for his opinions. *Id.* at 7-9. In deposition, Rafalski stated that, in forming these opinions, in addition to his training and experience, he applied “legal guidance” that he received from the DEA’s attorneys during his tenure there. Defs. Mtn. to Excl. Rafalski, Ex. 2 at 694:8 to 695:21 (“Rafalski Depo.”) (Doc. #: 1900-3). Citing *Touhy* regulations,⁷ however, Rafalski refused to

⁷ Often called “Touhy regulations,” the Code of Federal Regulations contain procedures for obtaining information from current and former DOJ employees. *See* 28 C.F.R.

disclose this legal guidance. *See id.* at 842:1-19. In light of this refusal, Rafalski may not testify as to these opinions. *See* Fed. R. Civ. P. 26(a)(2)(B) (expert report must contain a complete statement of all opinions the witness will express and the basis and reasons therefor); Fed. R. Civ. P. 37(c) (if a party fails to provide information as required by Rule 26(a), the party may not use the information at trial “unless the failure was substantially justified or is harmless”).

Moreover, these same opinions constitute legal conclusions. It is the Court’s role to instruct the jury as to applicable principles of the law. *Shahid v. City of Detroit*, 889 F.2d 1543, 1547-1548 (6th Cir. 1989) (quoting *United States v. Zipkin*, 729 F.2d 384, 387 (6th Cir. 1984) (it is for the judge, not witness, to instruct the jury as to applicable principles of the law)). Although Rule 704(a) of the Federal Rules of Evidence does not preclude an opinion “just because it embraces an ultimate issue,” Fed. R. Evid. 704(a), the ultimate issue must be a factual one. *See Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994). In other words, an expert generally may not opine as to what the law requires, or whether Defendants’ conduct violated the law. *See id.* at 1353-54 (agreeing with other courts that require exclusion of expert testimony expressing a legal conclusion).

As the Sixth Circuit has explained:

When the rules speak of an expert’s testimony embracing the ultimate issue, the reference must be to stating opinions that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue. We would not allow a fingerprint expert in a criminal case to opine that a defendant was guilty (a legal conclusion), even though we would allow him to opine that the defendant’s fingerprint was the only one on the murder weapon (a fact). The distinction, although subtle, is nonetheless important.

§ 16.21 et seq.; *United States v. Lyimo*, 574 Fed. Appx. 667, 669 (6th Cir. 2014) (Congress has authorized federal agencies to create regulations governing conditions under which their employees may testify concerning their work) (citing *United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 468 (1951)) (further citations omitted).

Berry, 25 F.3d at 1353; *see also Torres v. Cty. of Oakland*, 758 F.2d 147, 150-51 (6th Cir. 1985) (testimony containing a legal conclusion invades the province of the court to determine the applicable law and instruct the jury regarding the law).

As a former Diversion Investigator, Rafalski clearly has experience and expertise regarding the components and characteristics he would expect to be included in an effective SOMS and due diligence program. Indeed, Defendants do not challenge his credentials in this regard. Rafalski, however, has no legal training and is not an expert in the law. Thus, to the extent Rafalski expresses opinions as to what the law requires, or whether Defendants' conduct violated the law, his opinions are not admissible. *See Berry*, 25 F.3d at 1353-54; *Torres*, 758 F.2d 147 at 150-51. The Court examines each of the challenged opinions below.

a. The law required Defendants to halt all shipments after identifying an initial suspicious order.

Defendants seek to preclude Rafalski from testifying that, after identifying an initial suspicious order, the law required Defendants to halt all shipments. As discussed, it is the Court's role to instruct the jury as to applicable principles of the law. *Shahid*, 889 F.2d at 1547-48. Indeed, the Court has already determined, as a matter of law, that the duty to maintain effective controls requires a registrant to: (1) identify suspicious orders of controlled substances; (2) report suspicious orders when discovered; and (3) decline to ship a suspicious order unless and until, through due diligence, the registrant determines the order is not likely to be diverted into illegal channels. *See Order on CSA Duties* at 15, 18-19 (Doc. #: 2483).

While Rafalski may refer to the law as instructed by this Court, he may not express his own opinions as to what the law requires. Additionally, based on his experience as a DEA Investigator, Rafalski may express opinions as to particular characteristics in SOMS and due diligence

procedures that he finds are effective in preventing diversion; however, he may not express an opinion regarding an ultimate legal conclusion on whether a Defendant's conduct violated the law. *See, e.g., Woods v. Lecureux*, 110 F.3d 1215, 1221 (6th Cir. 1997) (expert testimony that attempts to tell the jury what result to reach can hardly be viewed as being helpful to the jury). Thus, while Rafalski may testify as to why halting shipments after identifying a suspicious order is effective in preventing diversion, he may not state what the law requires or whether Defendants' conduct violated the law in this regard.

b. DEA regulations require certain "key components" in SOMS and due diligence systems.

Defendants ask the Court to preclude Rafalski from testifying that DEA regulations require certain "key components" to be part of a SOMS and due diligence system. These "key components" are based on what Rafalski would expect to see in "an operational system designed to maintain effective control against diversion." Rafalski Rpt. at ECF pp. 36-40 (Doc. #: 1999-21). Although Rafalski admitted the "key components" were not "requirements," he also testified that DEA regulations "required" the components. Rafalski Depo. at 441:10 to 442:9, 447:14-19, 448:13-24 (Doc. #: 1900-3). For reasons stated above, based on his training and experience, Rafalski may testify about what components he believes an effective SOMS should contain; however, he may not testify as to what the law requires or whether Defendants' conduct violated the law.

c. The CSA and its implementing regulations require Manufacturers to consider prescription and chargeback data.

Defendants ask the Court to disallow Rafalski's testimony that the CSA and its implementing regulations require Manufacturers to consider prescription and chargeback data. For reasons stated, Rafalski cannot express opinions as to what the law requires or whether Defendants' conduct violated the law.

d. DEA registrants must document and permanently retain suspicious order reports and due diligence records.

Defendants ask the Court to preclude Rafalski from stating that the law requires registrants to document and retain forever suspicious order reports and due diligence records. It is Rafalski's position that, while the regulations do not require a registrant to retain these documents for any specific length of time, in his opinion, permanent retention is important to maintaining effective control and preventing diversion. *See* Rafalski Depo. at 125:11 to 126:3. For the reasons stated above, Rafalski may opine as to the need for documentation to maintain effective control; however, he may not state what the law requires in this regard.

2. Methodology to Identify Suspicious Orders.

Defendants also challenge the methodology that Rafalski used to identify suspicious orders, asserting his methods are unreliable and based on the faulty premise that, following the first flagged order, the Distributor performed no due diligence – or inadequate due diligence – and, therefore, every subsequent order was suspicious and should not have been shipped. *See* Defs. Mem. on Rafalski at 9-12 (Doc. #: 1900-1).

a. Five Methods.

Rafalski advanced five, non-exclusive methods that a Distributor could use to flag potentially suspicious orders.⁸ According to Rafalski, once flagged, the orders should not be shipped unless due diligence eliminates the suspicion of diversion. *See* Rafalski Rpt. at ECF pp. 40-46 (Doc. #: 1999-21). Rafalski's five methods were provided to McCann, *see* Rafalski Depo. at 499:2:14, who applied them to the DEA's ARCOS data and Defendants' transactional data to determine the number of orders to the *Track One* Counties that each method would have flagged. Rafalski then used McCann's calculations to provide, for each method, a table showing the number of dosage units of Oxycodone and Hydrocodone the Distributors shipped to Cuyahoga and Summit Counties between 1996 and 2018, and the percentage of orders flagged based on the total of dosage units shipped. *See* Rafalski Rpt. at ECF pp. 41-46 (Doc. #: 1999-21).

Defendants argue the five methodologies are unreliable because Rafalski has not tested the results to determine if, in fact, they flagged orders that were actually suspicious. *See* Defs. Mem. on Rafalski at 9-11 (Doc. #: 1900-1). In response, Plaintiffs point out that some Defendants actually used Rafalski's methods in their own SOMS, and the D.C. Circuit has endorsed the "Maximum Monthly, Trailing 6-Month Threshold" as a reasonable method for flagging orders that meet the regulatory definition of "suspicious orders."⁹ *See* Rafalski Rpt. at ECF pp. 41-42, 47 (Doc. #: 1999-21) (one or more of the Defendants used at least some of the methods); *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 216-17 (D.C. Cir. 2017) (as a matter of common sense and

⁸ The five methods are described below in the Court's analysis regarding McCann.

⁹ Rafalski also opines that the "Maximum Monthly, Trailing 6-Month Threshold" method provides "a reasonable estimate and an initial trigger and first step to identifying orders of unusual size." Rafalski Rpt. at ECF pp. 41-42, 47 (Doc. #: 1999-21).

ordinary language, orders that deviate from a six-month trend are an “unusual” and not “normal” occurrence).

As this Court has previously found, an order may be suspicious for any number of reasons, and there are many algorithms that a Distributor could use to identify opioid orders as suspicious. Discovery Ruling no. 12 (“DR-12”) at 2-3, n.2 (Doc. #: 1174); *see also* Order denying Daubert motion seeking to exclude Keller. Based on Rafalski’s extensive field experience as a DEA investigator reviewing the effectiveness of Distributors’ SOMS, the Court finds his expertise in identifying methodologies available to flag potentially suspicious orders is reliable. *See First Tennessee Bank Nat’l Ass’n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001) (where non-scientific expert testimony is involved, the relevant reliability concerns may focus on personal knowledge or experience). Moreover, in determining whether Defendants employed effective measures to identify, investigate, and stop shipment of suspicious orders, it would be helpful to the finder of fact to hear evidence about the number of suspicious orders that each methodology would have flagged. Accordingly, the Court concludes that Rafalski’s methodologies are reliable and would aid the jury’s determination of material issues in the case.

b. Assumption all Future Orders are Suspicious.

Defendants assert Rafalski has no basis to support his opinion that, once an order is flagged as suspicious, all subsequent orders from the same purchaser would be suspicious and should not be shipped. *See* Defs. Mem. on Rafalski at 11-12 (Doc. #: 1900-1). Plaintiffs respond that Rafalski’s analysis is reliable because it is based on his extensive review of Defendants’ SOMS programs, after which he concluded that Defendants conducted little or no due diligence (which is based, at least in part, on their failure to report suspicious orders and/or document due diligence).

See Pls. Resp. at 13-15 (Doc. #: 2112).¹⁰ Defendants reply that, if the law does not *require* them to maintain due diligence records, Rafalski has no credible basis to conclude they did not conduct due diligence based on the absence of those records. Defs. Reply on Rafalski at 4-5 (Doc. #: 2478).¹¹ Based on his experience as a DEA Diversion Investigator, however, Rafalski may opine as to what the absence of due diligence records indicates to him.¹² Moreover, it is notable that Defendants do not contradict Rafalski by explaining they did conduct due diligence but don't have any documents to support it.

Rafalski also opines that, if a Distributor fails to investigate a suspicious order, all future orders from the same customer remain suspicious unless, as a result of due diligence, the suspicion concerning the first order has been dispelled. *See* Rafalski Rpt. at ECF p. 40 (Doc. #: 1999-21).

Specifically, Rafalski states:

Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk.

Id.

¹⁰ Doc. #: 2112 is the Notice of Service for Plaintiffs' Consolidated Response Brief regarding Rafalski and McCann.

¹¹ Doc. #: 2478 is the Notice of Service for Defendants' Reply Brief regarding Rafalski.

¹² The Court notes whether an order is "suspicious," the timing of when it is "discovered," and whether a registrant conducted due diligence that adequately dispelled the suspicion involve questions of fact that will necessarily depend on the totality of individual circumstances. *See, e.g.*, Order on CSA Duties at 15, 20-31 (Doc. #: 2483).

Rafalski's extensive experience investigating the effectiveness of Distributors' SOMS provides a reliable basis for this opinion. *See Barreto*, 268 F.3d at 335. Defendants argue that, "[b]y flagging almost everything, Rafalski's method fails to highlight much of anything for further scrutiny," Defs. Mem. on Rafalski at 11 (Doc. #: 1900-1); however, their argument goes to the weight of his opinion, not its admissibility. *See United States v. L.E. Cooke Co.*, 991 F.2d 336, 342 (6th Cir.1993) (challenges to the accuracy of an expert's conclusions or factual basis generally "bear on the weight of the evidence rather than on its admissibility"). Defendants may argue to the jury that Rafalski's method is over-inclusive and only the first order flagged as suspicious requires due diligence, not every other order placed thereafter.

Based on the foregoing analysis, the Court finds that Rafalski's opinions provide relevant evidence regarding whether Defendants maintained effective control against diversion including whether they adequately identified, investigated, and/or stopped shipment of suspicious orders. *See* Pls. Resp. at 14 (Doc. #: 2112). Of course, Defendants are free to demonstrate at trial that, under the circumstances, the orders were not suspicious, they performed adequate due diligence, and/or it was otherwise reasonable for them to ship subsequent orders.

3. All Suspicious Orders were Diverted for Illicit Use.

Defendants object to Rafalski's deposition testimony that, if an order is identified as suspicious, "that puts it as a probable, greater than 51% that it's going to be diverted." Defs. Mem. on Rafalski at 14 (Doc. #: 1900-1) (quoting Rafalski Depo. at 189:18-24 (Doc. #: 1900-3)). Plaintiffs concede this statement is not in Rafalski's report and he does not intend to testify to it at trial. Pls. Resp. at 25 (Doc. #: 2112). In light of Plaintiffs' response, Defendants' argument on this issue is moot.

II. McCann.

A. Credentials and Experience.

McCann received a Ph.D. in economics from the University of California at Los Angeles in 1989. *See* McCann Rpt. at 2, appx. 1 (Doc. #: 1999-13).¹³ Throughout the 1990s, he taught graduate-level economics and finance courses at the University of South Carolina (1987 to 1992), Virginia Tech (1995 to 1997), Georgetown University (1996), and the University of Maryland (1995 to 1998). *See id.*, appx. 1. In addition, he served as an academic fellow for the U.S. Securities and Exchange Commission. *See id.*

Since 1999, McCann's primary occupation has been to provide expert consultation and testimony in complex litigation involving securities class actions, investment management, labor, and valuation disputes. *See id.* Defendants do not challenge McCann's qualifications as an expert.

B. Opinions.

McCann applied Rafalski's five methods to the DEA's ARCOS data and Defendants' transactional data to identify suspicious transactions for specific Defendants, as described below. *See* Defs. Mtn. to Excl. McCann, Ex. 4 at 134:13-17 ("McCann Depo.") (Doc. #: 1906-8). For each method, McCann calculated the results separately for 12 controlled substance drug codes shipped to Cuyahoga and Summit counties. *See id.* at 56-81. Also, for each method, McCann assumed the Distributor did not adequately investigate the first flagged order and, therefore, all subsequent orders relating to the same drug code were also suspicious. Specifically, for each

¹³ McCann's Report is also filed as an exhibit to Defendants' Motion. *See* Defs. Mtn. to Excl. McCann, Ex. 1 (Doc. #: 1906-5). However, the Report filed there is missing pages 8 to 55. *See id.* Accordingly, the Court cites to the Report that Plaintiffs filed as an exhibit to their Notice of Corrected Filing of Expert Reports. *See* Notice, Ex. 13 (Doc. #: 1999-13).

method, after flagging one transaction for a particular Defendant, McCann then flagged all of that Defendant's subsequent transactions for that particular drug code, based on the assumption that "the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction." McCann Rpt. at 56-57, 60, 64, 68, 72 (Doc. #: 1999-13).¹⁴

1. Maximum Monthly, Trailing 6-Month Threshold.

The first method identified transactions that cause "the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed the highest number of dosage units shipped by the Distributor to the Pharmacy in any one of the six preceding calendar months." McCann Rpt. at 56 (Doc. #: 1999-13). Using this method, McCann flagged 76 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 75.4 percent of the transactions shipped into Summit County during the same time period. *See id.* at 57-58.

2. 2X Trailing 12-Month Average Pharmacy Dosage Units.

The second method tracked transactions that cause "the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor." *Id.* at 60. Using this method, McCann flagged 45.6 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 62.9 percent of the transactions shipped into Summit County during the same time period. *See id.* at 61-62.

¹⁴ McCann also expresses opinions that: (1) the ARCOS data produced by the DEA is complete and reliable; and (2) except for the data produced by ABDC, the transactional data produced by Defendants is reliable. *See* McCann Rpt. at 4-6, 7-55 (Doc. #: 1999-13). Defendants do not challenge these portions of his Report.

3. 3X Trailing 12-Month Average Pharmacy Dosage Units.

The third method marked transactions that cause “the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed three times the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor.” *Id.* at 64. Using this method, McCann flagged 26.0 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 40.5 percent of the transactions shipped into Summit County during the same time period. *See id.* at 65-66.

4. Maximum 8,000 Dosage Units Monthly.

The fourth method identified transactions that cause “the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed 8,000 dosage units.” *Id.* at 68. Using this method, McCann flagged 42.6 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 52.4 percent of the transactions shipped into Summit County during the same time period. *See id.* at 68-69.

5. Maximum Daily Dosage Units.

The fifth method marked transactions that cause “the number of dosage units shipped by a Distributor to a Pharmacy in a day to exceed a number of dosage dosage [sic] units that varies by drug type and within some drug types by formulation.” *Id.* at 72. For example, the daily dosage flag used by this fifth method for MS Contin is 600 tabs for hospitals and 500 tabs for retail pharmacies. Using this method, McCann flagged 83.3 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 86.8 percent of the transactions shipped into Summit County during the same time period. *See id.* at 73.

C. Analysis.

Defendants urge the Court to exclude McCann's opinions on grounds they do not "fit" with issues in the case and, therefore, would not be helpful to the jury. Defendants also complain about the way that McCann applied Rafalski's methods to the ARCOS and transactional data. For the reasons set forth below, the Court disagrees with Defendants' contentions.

1. Fit.

Defendants contend that, because the law does not *require* registrants to use any of Rafalski's methods, the orders that McCann flagged have no bearing on, or do not "fit" with, issues in the case. *See* Defs. Mem. on McCann at 7-11 (Doc. #: 1906-2). More specifically, Defendants assert that, because the law allows them to craft their own procedures to identify suspicious orders based on individual circumstances, McCann's analysis in applying Rafalski's methods to their transactional data is irrelevant. While the Court agrees that an order may be suspicious for any number of reasons and there are many algorithms available to identify opioid orders as suspicious, *see* Discovery Ruling no. 12 ("DR-12") at 2-3, n.2 (Doc. #: 1174), Defendants ignore the fact that Distributors have a uniform obligation to maintain effective control against diversion, including duties to identify suspicious orders and decline to ship them unless and until, through due diligence, the Distributor can determine the order is not likely to be diverted into illegal channels. *See* Order on CSA Duties at 1, 15, 18-19 (Doc. #: 2483).

Rafalski's opinions regarding methods that are *available* to Distributors to flag potentially suspicious orders, including McCann's application of those methods to Defendants' data, are both relevant and helpful to resolving issues in this case, including: (1) whether Defendants employed reasonable measures to identify potentially suspicious orders; (2) the number of orders Defendants could have reasonably flagged; and (3) whether Defendants conducted adequate due diligence to

stop shipment of suspicious orders. Of course, at trial, Defendants may show, based on individual circumstances, why Rafalski's methods may not have been appropriate for them to use, or why other methods were equally or more effective. On this record, the Court finds that McCann's opinions are relevant and would aid the jury's determination of material issues in the case. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993) (court must perform a case-by-case assessment to determine whether a particular expert's testimony will truly help the jury to understand the evidence).¹⁵

2. Application.

Defendants also challenge the manner in which McCann applied Rafalski's methodologies. First, they assert McCann applied the methods incorrectly, noting Rafalski's instructions called for the use of a national average but, for several Defendants, McCann used county averages instead. *See* Defs. Mem. on McCann at 13 (Doc. #: 1906-2). Plaintiffs respond that McCann used the best information available. *See* Pls. Resp. at 26 (Doc. #: 2112). The Court finds this argument goes to the weight of the evidence, not its admissibility. *See L.E. Cooke*, 991 F.2d at 342.

Next, Defendants contend McCann unilaterally altered one of Rafalski's methods and used a different methodology instead. Defendants assert that, in interrogatory responses and at deposition, Rafalski identified one of his five methods as the "Common Sense Method Two ('Exceeding Threshold of Initial 6 Months and Assuming No Due Diligence')," which does not appear in the McCann or Rafalski reports. Defs. Mem. on McCann at 13-14 (Doc. #: 1906-2).

¹⁵ For reasons stated above with respect to Rafalski, the Court rejects Defendants' challenge to McCann's assumption that, after flagging one order, all subsequent orders are suspicious and should not have been shipped. *See* Defs. Mem. on McCann at 11-12 (Doc. #: 1906-2). The viability of this assumption goes to weight and not admissibility.

Defendants argue McCann substituted the “Maximum Daily Dosage Units” method instead. *Id.* According to Defendants, this shows “McCann’s flagged transactions do not reflect suspicious orders according to Rafalski’s actual methods and do not fit any issues in the case.”¹⁶ *Id.* at 14. Plaintiffs dismiss this argument, pointing to the fact that Rafalski clearly embraced the “Maximum Daily Dosage Units” method applied by McCann. *See* Rafalski Rpt., at ECF p. 45-46 (Doc. #: 1999-21). Regardless who is correct, defendants’ argument goes to the weight of the opinion, not its admissibility. The parties can argue this minor aspect of methodology at trial. *See Cooke*, 991 F.2d at 342.

Finally, Defendants complain that McCann provided his flagging analysis only in the aggregate across all Defendants, making it impossible to determine how many flagged orders a particular Distributor shipped to an individual customer. Defs. Mem. on McCann at 13-14 (Doc. #: Doc. #: 1906-2). Plaintiffs deny the contention, stating they provided Defendants with Excel files containing every Distributor transaction in the *Track One* Counties, along with “five columns which indicate whether each transaction passed or failed each of the five methodologies.” Pls. Resp. at 26 (Doc. #: 2112). Defendants reply that McCann provided aggregate data *to Rafalski* and, thus, Rafalski could not analyze particular orders. Defs. Reply on McCann at 8 (Doc. #:

¹⁶ In their reply brief, Defendants switch gears and state their argument was really “that this method was not disclosed in Plaintiffs’ interrogatory responses, where Plaintiffs were required to disclose the method they were using, and which [sic] Rafalski testified included his five methods.” Defs. Reply on McCann at 8 (Doc. #: 2442). The Court disagrees. In support of their motion, Defendants stated Rafalski testified regarding the “Common Sense Method Two,” which also appeared in Plaintiffs’ interrogatory responses; but Defendants did not urge exclusion based on a failure to disclose. *See* Defs. Mem. on McCann at 13-14 (Doc. #: 1906-2). The Court declines to address arguments raised for the first time in Defendants’ reply brief. *See, e.g., Ross v. Choice Hotels Int’l, Inc.*, 882 F. Supp.2d 951 (S.D. Ohio 2012) (“a reply brief is not the proper place to raise an issue for the first time”) (citations omitted). Nevertheless, the Court notes that, at most, Defendants’ new argument relates to only one of the five methods in McCann’s Report.

2442). Rafalski, however, does not offer opinions regarding particular orders. On this record, the Court declines to exclude McCann's opinions.

III. Conclusion.

For the foregoing reasons, Defendants' Motion to Exclude the Opinions Offered by James Rafalski (**Doc. #: 1900**) is **GRANTED IN PART**: Rafalski may not offer expert testimony as to the following opinions: (1) the law required defendants to halt all shipments after identifying an initial suspicious order; (2) DEA regulations require certain "key components" regarding SOMS and due diligence systems; (3) the CSA and its implementing regulations require Manufacturers to consider prescription and chargeback data; and (4) the law requires DEA registrants to document and permanently retain suspicious order reports and due diligence records. Defendants' Motion to Exclude Rafalski (**Doc. #: 1900**) is **DENIED** as to Rafalski's remaining opinions.

Additionally, for reasons stated above, Defendants' Motion to Exclude the Opinions and Testimony of Craig McCann (**Doc. #: 1906**) is **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster August 20, 2019
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF OHIO
EASTERN DIVISION

IN RE: NATIONAL PRESCRIPTION) MDL 2804
OPIATE LITIGATION)
) Case No. 1:17-md-2804
THIS DOCUMENT RELATES TO:)
) Judge Dan Aaron Polster
Track One Cases)
) OPINION AND ORDER REGARDING
) DEFENDANTS' MOTIONS TO
) EXCLUDE OPINIONS OF JAMES
) RAFALSKI AND CRAIG MCCANN

Before the Court are two related *Daubert* motions filed by Defendants: (1) a Motion to Exclude the Opinions Offered by James Rafalski (**Doc. #: 1900**); and (2) a Motion to Exclude the Opinions and Testimony of Craig McCann (**Doc. #: 1906**). For the reasons stated below, the Court **GRANTS IN AND DENIES IN PART** the Motion to Exclude Rafalski (**Doc. #: 1900**) and **DENIES** the Motion to Exclude McCann (**Doc. #: 1906**).

* * * * *

Rafalski, a former Drug Enforcement Administration (“DEA”) investigator, offers opinions about, *inter alia*, the effectiveness of Defendants’ efforts to prevent the diversion of controlled substances into illegitimate channels. Rafalski identified five methods that a Distributor could use to identify potentially suspicious orders. In turn, McCann, a data expert, applied Rafalski’s methods to the DEA’s Automation of Reports and Consolidation Orders System (“ARCOS”) data and Defendants’ transactional data to identify transactions that meet the specified criteria of each methodology. Taken together, Rafalski and McCann provide opinions, as to

specific Defendants, regarding the number of orders to the *Track One* Counties that each method would have flagged as potentially suspicious.

Defendants ask the Court to exclude both opinions for a number of reasons, including unreliability, flawed assumptions, and lack of “fit” with issues in the case. Also, as to four of Rafalski’s opinions, Defendants assert Rafalski has not disclosed the basis for the opinions and may not testify as to legal conclusions. The Court agrees Rafalski must disclose the basis for his opinions, and he may not opine as to what the law requires or whether Defendants’ conduct violated the law. As to Rafalski’s remaining opinions, the Court finds Defendants’ attacks are unfounded. The Court’s reasoning is set forth below.

I. Rafalski.

A. Credentials and Experience.

Rafalski received an undergraduate degree in public administration from Eastern Michigan University in 1999. Rafalski Rpt., at ECF p. 4 (Doc. #: 1999-21).¹ In 2004, after 26 years as a law enforcement officer, Rafalski began work for the DEA as a Diversion Investigator in the Detroit Divisional Office, where he worked until June of 2017. *Id.* Diversion Investigators are responsible for conducting regulatory, state, civil, administrative, and criminal investigations. *Id.* From 2011 to 2017, Rafalski was primarily responsible for conducting administrative, civil, and regulatory investigations of DEA registrants. *Id.* In this capacity, he investigated the criminal

¹ Rafalski’s Report is also filed as an exhibit to Defendants’ Motion. *See* Defs. Mtn. to Excl. Rafalski, Ex. 1 (Doc. #: 1900-2). However, that document is missing pages 47 to 144. *See id.* Accordingly, the Court cites to the Report that Plaintiffs filed as an exhibit to their Notice of Corrected Filing of Expert Reports. *See* Notice, Ex. 21 (Doc. #: 1999-21). Because Doc. #: 1999-21 does not contain page numbers, the Court cites to the electronic court filing (“ECF”) pages.

conduct of individual physicians regarding improper opioid prescriptions and conducted regulatory investigations involving, *inter alia*, Distributors' compliance with DEA requirements regarding suspicious order monitoring systems ("SOMS"). *Id.* at ECF pp. 4-5.

For example, in 2006, Rafalski conducted an accountability audit, record-keeping review, and security investigation of a Walgreens in Ohio to ensure compliance with controlled substances regulations and record keeping. *Id.* at ECF p. 5. This investigation resulted in the DEA issuing a letter of admonition for the maintenance of an inadequate SOMS. *Id.*

From 2010 to 2013, Rafalski conducted an administrative investigation of The Harvard Drug Group to identify unusual patterns of distribution of oxycodone to Florida pain clinics. *Id.* at ECF p. 6. His work included the review of company records and policies, as well as the DEA's ARCOS data. *Id.* This investigation resulted in the DEA issuing an order to show cause for, *inter alia*, developing a work-around to avoid triggering the company's SOMS. *Id.*

Also, from 2010 to 2013, Rafalski conducted an administrative investigation of Masters Pharmaceutical, reviewing company files regarding customer due diligence, including questionnaires, on-site investigation reports, and SOMS information. This investigation resulted in the DEA revoking the company's registration to manufacture and/or distribute controlled substances. *Id.*; see *Masters Pharm., Inc. v. DEA*, 861 F.3d 206 (D.C. Cir. 2017).

From 2010 to 2017, Rafalski conducted an administrative investigation of Mallinckrodt in which he reviewed chargeback data² that revealed some pharmacies and/or practitioners were utilizing multiple Distributors to purchase the same product in large quantities. *Id.* at ECF pp. 6-

² According to Rafalski, chargeback data or fee-for-services data provided by Distributors allows a Manufacturer to determine who purchased its drugs, in what volumes, and in which doses. See Rafalski Rpt. at ECF p. 146 (Doc. #: 1999-21).

7. As a result of this investigation, the DEA and Mallinckrodt entered into a three-year Memorandum of Agreement. *Id.*

Defendants do not challenge Rafalski's qualifications as an expert.

B. Opinions.

Rafalski expresses opinions about the compliance requirements for Manufacturers and Distributors to: (1) maintain effective controls to prevent diversion of controlled substances into illegitimate channels; (2) design and operate a system to identify suspicious orders (SOMS); and (3) report suspicious orders "when discovered."³ Rafalski Rpt. at ECF p. 10 (Doc. #: 1999-21). His opinions address four main categories:

- (1) what the law and DEA regulations require regarding the duties of Manufacturers and Distributors to maintain effective control against the diversion of controlled substances, *id.* at ECF pp. 9-21;⁴
- (2) key components and characteristics that make SOMS and due diligence programs effective, *id.* at ECF pp. 36-40;
- (3) five methodologies that, as calculated by Craig McCann (discussed below), identify "suspicious orders" that Defendants should not have shipped without conducting due diligence to dispel the suspicion of diversion, *id.* at ECF pp. 40-46; and

³ Under federal regulations, "suspicious orders include [among others] orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency." 21 C.F.R. § 1301.74(b).

⁴ Rafalski also discusses industry guidelines and provides a list of 32 "significant" DEA administrative actions against various Manufacturers and Distributors for failing to maintain effective control against diversion and identify and/or report suspicious orders. Rafalski Rpt. at ECF pp. 21-36 (Doc. #: 1999-21).

(4) the SOMS and due diligence practices of various Defendants and how they failed to comply with statutory and regulatory duties to maintain effective control against diversion, *id.* at ECF pp. 46-187.

Rafalski examined in detail the SOMS and due diligence procedures of six Distributors, concluding each violated its duty to maintain effective control against diversion, including duties to identify, report and/or stop shipment of suspicious orders.⁵ *See* Rafalski Rpt. at ECF pp. 9, 54-55, 68-69, 77-81, 91-93, 104-105, 120-121, 142-144 (Doc. #: 1999-21). Rafalski opines that these SOMS failures “directly led to massive quantities of pills being shipped to buyers who had placed suspicious orders of controlled substances” that should never have been shipped “until after the suspicion of diversion was dispelled.” *Id.* at 40.

In addition, Rafalski examined the SOMS and due diligence procedures of seven Manufacturers, concluding each failed to meet its obligation to maintain effective controls against diversion.⁶ Rafalski opines that, to comply with their duty to maintain effective control, Manufacturers must use all relevant prescribing and chargeback data. *Id.* at ECF pp. 145-187.

C. Analysis.

Defendants ask the Court to exclude Rafalski’s testimony because: (1) he refused to disclose the basis for four of his opinions; (2) his methodology is based on faulty assumptions; and

⁵ The six Distributors are: Cardinal, McKesson, ABDC, CVS, Walgreen, and Henry Schein. Rafalski Rpt. at ECF pp. 46-145 (Doc. #: 1999-21). Rafalski selected these Distributors because, according to McCann’s calculations, they distributed a significant majority of the opioid pills delivered into Summit and Cuyahoga Counties. Rafalski Rpt. at 42 n.110 (Doc. #: 1999-21).

⁶ The seven Manufacturers are: Allergan, Janssen, Mallinckrodt, Purdue, Endo, Teva, and Insys. Rafalski Rpt. at ECF pp. 151-187 (Doc. #: 1999-21).

(3) he has no basis to conclude that all flagged orders were diverted for illicit use. *See* Defs. Mem. on Rafalski at 1 (Doc. #: 1900-1). The Court addresses each argument below.

1. Refusal to Disclose the Basis for Four Opinions.

Defendants urge the Court to exclude the following opinions because Rafalski has not disclosed the basis for them:

- (1) the law required Defendants to halt all shipments after identifying an initial suspicious order;
- (2) DEA regulations require certain “key components” regarding SOMS and due diligence systems;
- (3) the Controlled Substance Act (“CSA”) and its implementing regulations require Manufacturers to consider prescription and chargeback data; and
- (4) DEA registrants must document and permanently retain suspicious order reports and due diligence records.

See Defs. Mem. on Rafalski at 8 (Doc. #: 1900-1). Defendants also assert these opinions constitute impermissible legal conclusions. *Id.* at 8 n.3.

As to these four opinions, Defendants seek exclusion because Rafalski has refused to disclose the “legal guidance” he received from DEA attorneys that forms, at least in part, the basis for his opinions. *Id.* at 7-9. In deposition, Rafalski stated that, in forming these opinions, in addition to his training and experience, he applied “legal guidance” that he received from the DEA’s attorneys during his tenure there. Defs. Mtn. to Excl. Rafalski, Ex. 2 at 694:8 to 695:21 (“Rafalski Depo.”) (Doc. #: 1900-3). Citing *Touhy* regulations,⁷ however, Rafalski refused to

⁷ Often called “Touhy regulations,” the Code of Federal Regulations contain procedures for obtaining information from current and former DOJ employees. *See* 28 C.F.R.

disclose this legal guidance. *See id.* at 842:1-19. In light of this refusal, Rafalski may not testify as to these opinions. *See* Fed. R. Civ. P. 26(a)(2)(B) (expert report must contain a complete statement of all opinions the witness will express and the basis and reasons therefor); Fed. R. Civ. P. 37(c) (if a party fails to provide information as required by Rule 26(a), the party may not use the information at trial “unless the failure was substantially justified or is harmless”).

Moreover, these same opinions constitute legal conclusions. It is the Court’s role to instruct the jury as to applicable principles of the law. *Shahid v. City of Detroit*, 889 F.2d 1543, 1547-1548 (6th Cir. 1989) (quoting *United States v. Zipkin*, 729 F.2d 384, 387 (6th Cir. 1984) (it is for the judge, not witness, to instruct the jury as to applicable principles of the law)). Although Rule 704(a) of the Federal Rules of Evidence does not preclude an opinion “just because it embraces an ultimate issue,” Fed. R. Evid. 704(a), the ultimate issue must be a factual one. *See Berry v. City of Detroit*, 25 F.3d 1342, 1353 (6th Cir. 1994). In other words, an expert generally may not opine as to what the law requires, or whether Defendants’ conduct violated the law. *See id.* at 1353-54 (agreeing with other courts that require exclusion of expert testimony expressing a legal conclusion).

As the Sixth Circuit has explained:

When the rules speak of an expert’s testimony embracing the ultimate issue, the reference must be to stating opinions that suggest the answer to the ultimate issue or that give the jury all the information from which it can draw inferences as to the ultimate issue. We would not allow a fingerprint expert in a criminal case to opine that a defendant was guilty (a legal conclusion), even though we would allow him to opine that the defendant’s fingerprint was the only one on the murder weapon (a fact). The distinction, although subtle, is nonetheless important.

§ 16.21 et seq.; *United States v. Lyimo*, 574 Fed. Appx. 667, 669 (6th Cir. 2014) (Congress has authorized federal agencies to create regulations governing conditions under which their employees may testify concerning their work) (citing *United States ex rel. Touhy v. Ragen*, 340 U.S. 462, 468 (1951)) (further citations omitted).

Berry, 25 F.3d at 1353; *see also Torres v. Cty. of Oakland*, 758 F.2d 147, 150-51 (6th Cir. 1985) (testimony containing a legal conclusion invades the province of the court to determine the applicable law and instruct the jury regarding the law).

As a former Diversion Investigator, Rafalski clearly has experience and expertise regarding the components and characteristics he would expect to be included in an effective SOMS and due diligence program. Indeed, Defendants do not challenge his credentials in this regard. Rafalski, however, has no legal training and is not an expert in the law. Thus, to the extent Rafalski expresses opinions as to what the law requires, or whether Defendants' conduct violated the law, his opinions are not admissible. *See Berry*, 25 F.3d at 1353-54; *Torres*, 758 F.2d 147 at 150-51. The Court examines each of the challenged opinions below.

a. The law required Defendants to halt all shipments after identifying an initial suspicious order.

Defendants seek to preclude Rafalski from testifying that, after identifying an initial suspicious order, the law required Defendants to halt all shipments. As discussed, it is the Court's role to instruct the jury as to applicable principles of the law. *Shahid*, 889 F.2d at 1547-48. Indeed, the Court has already determined, as a matter of law, that the duty to maintain effective controls requires a registrant to: (1) identify suspicious orders of controlled substances; (2) report suspicious orders when discovered; and (3) decline to ship a suspicious order unless and until, through due diligence, the registrant determines the order is not likely to be diverted into illegal channels. *See Order on CSA Duties* at 15, 18-19 (Doc. #: 2483).

While Rafalski may refer to the law as instructed by this Court, he may not express his own opinions as to what the law requires. Additionally, based on his experience as a DEA Investigator, Rafalski may express opinions as to particular characteristics in SOMS and due diligence

procedures that he finds are effective in preventing diversion; however, he may not express an opinion regarding an ultimate legal conclusion on whether a Defendant's conduct violated the law. *See, e.g., Woods v. Lecureux*, 110 F.3d 1215, 1221 (6th Cir. 1997) (expert testimony that attempts to tell the jury what result to reach can hardly be viewed as being helpful to the jury). Thus, while Rafalski may testify as to why halting shipments after identifying a suspicious order is effective in preventing diversion, he may not state what the law requires or whether Defendants' conduct violated the law in this regard.

b. DEA regulations require certain “key components” in SOMS and due diligence systems.

Defendants ask the Court to preclude Rafalski from testifying that DEA regulations require certain “key components” to be part of a SOMS and due diligence system. These “key components” are based on what Rafalski would expect to see in “an operational system designed to maintain effective control against diversion.” Rafalski Rpt. at ECF pp. 36-40 (Doc. #: 1999-21). Although Rafalski admitted the “key components” were not “requirements,” he also testified that DEA regulations “required” the components. Rafalski Depo. at 441:10 to 442:9, 447:14-19, 448:13-24 (Doc. #: 1900-3). For reasons stated above, based on his training and experience, Rafalski may testify about what components he believes an effective SOMS should contain; however, he may not testify as to what the law requires or whether Defendants' conduct violated the law.

c. The CSA and its implementing regulations require Manufacturers to consider prescription and chargeback data.

Defendants ask the Court to disallow Rafalski's testimony that the CSA and its implementing regulations require Manufacturers to consider prescription and chargeback data. For reasons stated, Rafalski cannot express opinions as to what the law requires or whether Defendants' conduct violated the law.

d. DEA registrants must document and permanently retain suspicious order reports and due diligence records.

Defendants ask the Court to preclude Rafalski from stating that the law requires registrants to document and retain forever suspicious order reports and due diligence records. It is Rafalski's position that, while the regulations do not require a registrant to retain these documents for any specific length of time, in his opinion, permanent retention is important to maintaining effective control and preventing diversion. *See* Rafalski Depo. at 125:11 to 126:3. For the reasons stated above, Rafalski may opine as to the need for documentation to maintain effective control; however, he may not state what the law requires in this regard.

2. Methodology to Identify Suspicious Orders.

Defendants also challenge the methodology that Rafalski used to identify suspicious orders, asserting his methods are unreliable and based on the faulty premise that, following the first flagged order, the Distributor performed no due diligence – or inadequate due diligence – and, therefore, every subsequent order was suspicious and should not have been shipped. *See* Defs. Mem. on Rafalski at 9-12 (Doc. #: 1900-1).

a. Five Methods.

Rafalski advanced five, non-exclusive methods that a Distributor could use to flag potentially suspicious orders.⁸ According to Rafalski, once flagged, the orders should not be shipped unless due diligence eliminates the suspicion of diversion. *See* Rafalski Rpt. at ECF pp. 40-46 (Doc. #: 1999-21). Rafalski's five methods were provided to McCann, see Rafalski Depo. at 499:2:14, who applied them to the DEA's ARCOS data and Defendants' transactional data to determine the number of orders to the *Track One* Counties that each method would have flagged. Rafalski then used McCann's calculations to provide, for each method, a table showing the number of dosage units of Oxycodone and Hydrocodone the Distributors shipped to Cuyahoga and Summit Counties between 1996 and 2018, and the percentage of orders flagged based on the total of dosage units shipped. *See* Rafalski Rpt. at ECF pp. 41-46 (Doc. #: 1999-21).

Defendants argue the five methodologies are unreliable because Rafalski has not tested the results to determine if, in fact, they flagged orders that were actually suspicious. *See* Defs. Mem. on Rafalski at 9-11 (Doc. #: 1900-1). In response, Plaintiffs point out that some Defendants actually used Rafalski's methods in their own SOMS, and the D.C. Circuit has endorsed the "Maximum Monthly, Trailing 6-Month Threshold" as a reasonable method for flagging orders that meet the regulatory definition of "suspicious orders."⁹ *See* Rafalski Rpt. at ECF pp. 41-42, 47 (Doc. #: 1999-21) (one or more of the Defendants used at least some of the methods); *Masters Pharm., Inc. v. DEA*, 861 F.3d 206, 216-17 (D.C. Cir. 2017) (as a matter of common sense and

⁸ The five methods are described below in the Court's analysis regarding McCann.

⁹ Rafalski also opines that the "Maximum Monthly, Trailing 6-Month Threshold" method provides "a reasonable estimate and an initial trigger and first step to identifying orders of unusual size." Rafalski Rpt. at ECF pp. 41-42, 47 (Doc. #: 1999-21).

ordinary language, orders that deviate from a six-month trend are an “unusual” and not “normal” occurrence).

As this Court has previously found, an order may be suspicious for any number of reasons, and there are many algorithms that a Distributor could use to identify opioid orders as suspicious. Discovery Ruling no. 12 (“DR-12”) at 2-3, n.2 (Doc. #: 1174); *see also* Order denying Daubert motion seeking to exclude Keller. Based on Rafalski’s extensive field experience as a DEA investigator reviewing the effectiveness of Distributors’ SOMS, the Court finds his expertise in identifying methodologies available to flag potentially suspicious orders is reliable. *See First Tennessee Bank Nat’l Ass’n v. Barreto*, 268 F.3d 319, 335 (6th Cir. 2001) (where non-scientific expert testimony is involved, the relevant reliability concerns may focus on personal knowledge or experience). Moreover, in determining whether Defendants employed effective measures to identify, investigate, and stop shipment of suspicious orders, it would be helpful to the finder of fact to hear evidence about the number of suspicious orders that each methodology would have flagged. Accordingly, the Court concludes that Rafalski’s methodologies are reliable and would aid the jury’s determination of material issues in the case.

b. Assumption all Future Orders are Suspicious.

Defendants assert Rafalski has no basis to support his opinion that, once an order is flagged as suspicious, all subsequent orders from the same purchaser would be suspicious and should not be shipped. *See* Defs. Mem. on Rafalski at 11-12 (Doc. #: 1900-1). Plaintiffs respond that Rafalski’s analysis is reliable because it is based on his extensive review of Defendants’ SOMS programs, after which he concluded that Defendants conducted little or no due diligence (which is based, at least in part, on their failure to report suspicious orders and/or document due diligence).

See Pls. Resp. at 13-15 (Doc. #: 2112).¹⁰ Defendants reply that, if the law does not *require* them to maintain due diligence records, Rafalski has no credible basis to conclude they did not conduct due diligence based on the absence of those records. Defs. Reply on Rafalski at 4-5 (Doc. #: 2478).¹¹ Based on his experience as a DEA Diversion Investigator, however, Rafalski may opine as to what the absence of due diligence records indicates to him.¹² Moreover, it is notable that Defendants do not contradict Rafalski by explaining they did conduct due diligence but don't have any documents to support it.

Rafalski also opines that, if a Distributor fails to investigate a suspicious order, all future orders from the same customer remain suspicious unless, as a result of due diligence, the suspicion concerning the first order has been dispelled. See Rafalski Rpt. at ECF p. 40 (Doc. #: 1999-21).

Specifically, Rafalski states:

Any order that is suspicious requires action to dispel suspicion and confirm legitimacy. Otherwise the order should not ship. When a distributor neglects to dispel suspicion and ships anyway, the risk of diversion does not disappear when the order ships. For this reason, any future order or shipment to that particular pharmacy or buyer should not ship until an investigation of the initial suspicious order occurs because there is an outstanding concern about the past shipment that has not been addressed. Otherwise, a distributor is potentially sending larger and larger quantities of controlled substances to a buyer that is under suspicion of being a diversion risk.

Id.

¹⁰ Doc. #: 2112 is the Notice of Service for Plaintiffs' Consolidated Response Brief regarding Rafalski and McCann.

¹¹ Doc. #: 2478 is the Notice of Service for Defendants' Reply Brief regarding Rafalski.

¹² The Court notes whether an order is "suspicious," the timing of when it is "discovered," and whether a registrant conducted due diligence that adequately dispelled the suspicion involve questions of fact that will necessarily depend on the totality of individual circumstances. See, e.g., Order on CSA Duties at 15, 20-31 (Doc. #: 2483).

Rafalski's extensive experience investigating the effectiveness of Distributors' SOMS provides a reliable basis for this opinion. *See Barreto*, 268 F.3d at 335. Defendants argue that, "[b]y flagging almost everything, Rafalski's method fails to highlight much of anything for further scrutiny," Defs. Mem. on Rafalski at 11 (Doc. #: 1900-1); however, their argument goes to the weight of his opinion, not its admissibility. *See United States v. L.E. Cooke Co.*, 991 F.2d 336, 342 (6th Cir.1993) (challenges to the accuracy of an expert's conclusions or factual basis generally "bear on the weight of the evidence rather than on its admissibility"). Defendants may argue to the jury that Rafalski's method is over-inclusive and only the first order flagged as suspicious requires due diligence, not every other order placed thereafter.

Based on the foregoing analysis, the Court finds that Rafalski's opinions provide relevant evidence regarding whether Defendants maintained effective control against diversion including whether they adequately identified, investigated, and/or stopped shipment of suspicious orders. *See* Pls. Resp. at 14 (Doc. #: 2112). Of course, Defendants are free to demonstrate at trial that, under the circumstances, the orders were not suspicious, they performed adequate due diligence, and/or it was otherwise reasonable for them to ship subsequent orders.

3. All Suspicious Orders were Diverted for Illicit Use.

Defendants object to Rafalski's deposition testimony that, if an order is identified as suspicious, "that puts it as a probable, greater than 51% that it's going to be diverted." Defs. Mem. on Rafalski at 14 (Doc. #: 1900-1) (quoting Rafalski Depo. at 189:18-24 (Doc. #: 1900-3)). Plaintiffs concede this statement is not in Rafalski's report and he does not intend to testify to it at trial. Pls. Resp. at 25 (Doc. #: 2112). In light of Plaintiffs' response, Defendants' argument on this issue is moot.

II. McCann.

A. Credentials and Experience.

McCann received a Ph.D. in economics from the University of California at Los Angeles in 1989. *See* McCann Rpt. at 2, appx. 1 (Doc. #: 1999-13).¹³ Throughout the 1990s, he taught graduate-level economics and finance courses at the University of South Carolina (1987 to 1992), Virginia Tech (1995 to 1997), Georgetown University (1996), and the University of Maryland (1995 to 1998). *See id.*, appx. 1. In addition, he served as an academic fellow for the U.S. Securities and Exchange Commission. *See id.*

Since 1999, McCann's primary occupation has been to provide expert consultation and testimony in complex litigation involving securities class actions, investment management, labor, and valuation disputes. *See id.* Defendants do not challenge McCann's qualifications as an expert.

B. Opinions.

McCann applied Rafalski's five methods to the DEA's ARCOS data and Defendants' transactional data to identify suspicious transactions for specific Defendants, as described below. *See* Defs. Mtn. to Excl. McCann, Ex. 4 at 134:13-17 ("McCann Depo.") (Doc. #: 1906-8). For each method, McCann calculated the results separately for 12 controlled substance drug codes shipped to Cuyahoga and Summit counties. *See id.* at 56-81. Also, for each method, McCann assumed the Distributor did not adequately investigate the first flagged order and, therefore, all subsequent orders relating to the same drug code were also suspicious. Specifically, for each

¹³ McCann's Report is also filed as an exhibit to Defendants' Motion. *See* Defs. Mtn. to Excl. McCann, Ex. 1 (Doc. #: 1906-5). However, the Report filed there is missing pages 8 to 55. *See id.* Accordingly, the Court cites to the Report that Plaintiffs filed as an exhibit to their Notice of Corrected Filing of Expert Reports. *See* Notice, Ex. 13 (Doc. #: 1999-13).

method, after flagging one transaction for a particular Defendant, McCann then flagged all of that Defendant's subsequent transactions for that particular drug code, based on the assumption that "the Distributor had an unfulfilled obligation to detect and investigate the first flagged transaction." McCann Rpt. at 56-57, 60, 64, 68, 72 (Doc. #: 1999-13).¹⁴

1. Maximum Monthly, Trailing 6-Month Threshold.

The first method identified transactions that cause "the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed the highest number of dosage units shipped by the Distributor to the Pharmacy in any one of the six preceding calendar months." McCann Rpt. at 56 (Doc. #: 1999-13). Using this method, McCann flagged 76 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 75.4 percent of the transactions shipped into Summit County during the same time period. *See id.* at 57-58.

2. 2X Trailing 12-Month Average Pharmacy Dosage Units.

The second method tracked transactions that cause "the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed twice the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor." *Id.* at 60. Using this method, McCann flagged 45.6 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 62.9 percent of the transactions shipped into Summit County during the same time period. *See id.* at 61-62.

¹⁴ McCann also expresses opinions that: (1) the ARCOS data produced by the DEA is complete and reliable; and (2) except for the data produced by ABDC, the transactional data produced by Defendants is reliable. *See* McCann Rpt. at 4-6, 7-55 (Doc. #: 1999-13). Defendants do not challenge these portions of his Report.

3. 3X Trailing 12-Month Average Pharmacy Dosage Units.

The third method marked transactions that cause “the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed three times the trailing twelve-month average dosage units to retail and chain pharmacies served by the Distributor.” *Id.* at 64. Using this method, McCann flagged 26.0 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 40.5 percent of the transactions shipped into Summit County during the same time period. *See id.* at 65-66.

4. Maximum 8,000 Dosage Units Monthly.

The fourth method identified transactions that cause “the number of dosage units shipped by a Distributor to a Pharmacy in a calendar month to exceed 8,000 dosage units.” *Id.* at 68. Using this method, McCann flagged 42.6 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 52.4 percent of the transactions shipped into Summit County during the same time period. *See id.* at 68-69.

5. Maximum Daily Dosage Units.

The fifth method marked transactions that cause “the number of dosage units shipped by a Distributor to a Pharmacy in a day to exceed a number of dosage dosage [sic] units that varies by drug type and within some drug types by formulation.” *Id.* at 72. For example, the daily dosage flag used by this fifth method for MS Contin is 600 tabs for hospitals and 500 tabs for retail pharmacies. Using this method, McCann flagged 83.3 percent of the transactions shipped into Cuyahoga County from 1996 to 2018 and 86.8 percent of the transactions shipped into Summit County during the same time period. *See id.* at 73.

C. Analysis.

Defendants urge the Court to exclude McCann's opinions on grounds they do not "fit" with issues in the case and, therefore, would not be helpful to the jury. Defendants also complain about the way that McCann applied Rafalski's methods to the ARCOS and transactional data. For the reasons set forth below, the Court disagrees with Defendants' contentions.

1. Fit.

Defendants contend that, because the law does not *require* registrants to use any of Rafalski's methods, the orders that McCann flagged have no bearing on, or do not "fit" with, issues in the case. *See* Defs. Mem. on McCann at 7-11 (Doc. #: 1906-2). More specifically, Defendants assert that, because the law allows them to craft their own procedures to identify suspicious orders based on individual circumstances, McCann's analysis in applying Rafalski's methods to their transactional data is irrelevant. While the Court agrees that an order may be suspicious for any number of reasons and there are many algorithms available to identify opioid orders as suspicious, *see* Discovery Ruling no. 12 ("DR-12") at 2-3, n.2 (Doc. #: 1174), Defendants ignore the fact that Distributors have a uniform obligation to maintain effective control against diversion, including duties to identify suspicious orders and decline to ship them unless and until, through due diligence, the Distributor can determine the order is not likely to be diverted into illegal channels. *See* Order on CSA Duties at 1, 15, 18-19 (Doc. #: 2483).

Rafalski's opinions regarding methods that are *available* to Distributors to flag potentially suspicious orders, including McCann's application of those methods to Defendants' data, are both relevant and helpful to resolving issues in this case, including: (1) whether Defendants employed reasonable measures to identify potentially suspicious orders; (2) the number of orders Defendants could have reasonably flagged; and (3) whether Defendants conducted adequate due diligence to

stop shipment of suspicious orders. Of course, at trial, Defendants may show, based on individual circumstances, why Rafalski's methods may not have been appropriate for them to use, or why other methods were equally or more effective. On this record, the Court finds that McCann's opinions are relevant and would aid the jury's determination of material issues in the case. *See Daubert v. Merrell Dow Pharm., Inc.*, 509 U.S. 579, 591 (1993) (court must perform a case-by-case assessment to determine whether a particular expert's testimony will truly help the jury to understand the evidence).¹⁵

2. Application.

Defendants also challenge the manner in which McCann applied Rafalski's methodologies. First, they assert McCann applied the methods incorrectly, noting Rafalski's instructions called for the use of a national average but, for several Defendants, McCann used county averages instead. *See* Defs. Mem. on McCann at 13 (Doc. #: 1906-2). Plaintiffs respond that McCann used the best information available. *See* Pls. Resp. at 26 (Doc. #: 2112). The Court finds this argument goes to the weight of the evidence, not its admissibility. *See L.E. Cooke*, 991 F.2d at 342.

Next, Defendants contend McCann unilaterally altered one of Rafalski's methods and used a different methodology instead. Defendants assert that, in interrogatory responses and at deposition, Rafalski identified one of his five methods as the "Common Sense Method Two ('Exceeding Threshold of Initial 6 Months and Assuming No Due Diligence')," which does not appear in the McCann or Rafalski reports. Defs. Mem. on McCann at 13-14 (Doc. #: 1906-2).

¹⁵ For reasons stated above with respect to Rafalski, the Court rejects Defendants' challenge to McCann's assumption that, after flagging one order, all subsequent orders are suspicious and should not have been shipped. *See* Defs. Mem. on McCann at 11-12 (Doc. #: 1906-2). The viability of this assumption goes to weight and not admissibility.

Defendants argue McCann substituted the “Maximum Daily Dosage Units” method instead. *Id.* According to Defendants, this shows “McCann’s flagged transactions do not reflect suspicious orders according to Rafalski’s actual methods and do not fit any issues in the case.”¹⁶ *Id.* at 14. Plaintiffs dismiss this argument, pointing to the fact that Rafalski clearly embraced the “Maximum Daily Dosage Units” method applied by McCann. *See* Rafalski Rpt., at ECF p. 45-46 (Doc. #: 1999-21). Regardless who is correct, defendants’ argument goes to the weight of the opinion, not its admissibility. The parties can argue this minor aspect of methodology at trial. *See Cooke*, 991 F.2d at 342.

Finally, Defendants complain that McCann provided his flagging analysis only in the aggregate across all Defendants, making it impossible to determine how many flagged orders a particular Distributor shipped to an individual customer. Defs. Mem. on McCann at 13-14 (Doc. #: Doc. #: 1906-2). Plaintiffs deny the contention, stating they provided Defendants with Excel files containing every Distributor transaction in the *Track One* Counties, along with “five columns which indicate whether each transaction passed or failed each of the five methodologies.” Pls. Resp. at 26 (Doc. #: 2112). Defendants reply that McCann provided aggregate data *to Rafalski* and, thus, Rafalski could not analyze particular orders. Defs. Reply on McCann at 8 (Doc. #:

¹⁶ In their reply brief, Defendants switch gears and state their argument was really “that this method was not disclosed in Plaintiffs’ interrogatory responses, where Plaintiffs were required to disclose the method they were using, and which [sic] Rafalski testified included his five methods.” Defs. Reply on McCann at 8 (Doc. #: 2442). The Court disagrees. In support of their motion, Defendants stated Rafalski testified regarding the “Common Sense Method Two,” which also appeared in Plaintiffs’ interrogatory responses; but Defendants did not urge exclusion based on a failure to disclose. *See* Defs. Mem. on McCann at 13-14 (Doc. #: 1906-2). The Court declines to address arguments raised for the first time in Defendants’ reply brief. *See, e.g., Ross v. Choice Hotels Int’l, Inc.*, 882 F. Supp.2d 951 (S.D. Ohio 2012) (“a reply brief is not the proper place to raise an issue for the first time”) (citations omitted). Nevertheless, the Court notes that, at most, Defendants’ new argument relates to only one of the five methods in McCann’s Report.

2442). Rafalski, however, does not offer opinions regarding particular orders. On this record, the Court declines to exclude McCann's opinions.

III. Conclusion.

For the foregoing reasons, Defendants' Motion to Exclude the Opinions Offered by James Rafalski (**Doc. #: 1900**) is **GRANTED IN PART**: Rafalski may not offer expert testimony as to the following opinions: (1) the law required defendants to halt all shipments after identifying an initial suspicious order; (2) DEA regulations require certain "key components" regarding SOMS and due diligence systems; (3) the CSA and its implementing regulations require Manufacturers to consider prescription and chargeback data; and (4) the law requires DEA registrants to document and permanently retain suspicious order reports and due diligence records. Defendants' Motion to Exclude Rafalski (**Doc. #: 1900**) is **DENIED** as to Rafalski's remaining opinions.

Additionally, for reasons stated above, Defendants' Motion to Exclude the Opinions and Testimony of Craig McCann (**Doc. #: 1906**) is **DENIED**.

IT IS SO ORDERED.

/s/ Dan Aaron Polster August 20, 2019
DAN AARON POLSTER
UNITED STATES DISTRICT JUDGE